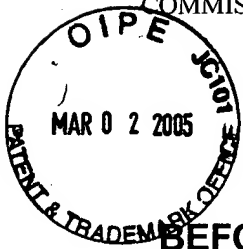


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AP/3738  
JTW



Date: 28 Feb. 2005

Gary J. Pizer

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent application

Applicant: Shlomo Gabbay Art Unit: 3738  
Serial No.: 09/973,609 Examiner: B. Pellegrino  
Filed: October 9, 2001  
Title: IMPLANTATION SYSTEM FOR IMPLANTATION OF A HEART  
VALVE PROSTHESIS

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P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY BRIEF**

Sir:

Following the Examiner's Answer dated December 28, 2004, Appellant presents this Reply Brief, filed in triplicate.

**1. Claims on Appeal:**

In number paragraph 11 under the heading "Response to Argument," the Examiner states that "applicant does not discuss the references applied against claims 20 through 28, 49 explain how the claims avoid the references or distinguish from them." As set forth in the issues paragraph and grouping of claims set forth in

applicant's appeal brief, claims 20 through 27 and 49 have not been appealed. To clarify, claims 2 through 19, 28, 50 and 53 through 57 are the subject of this appeal.

2. **It would not be obvious to modify the valve of Bessler et al. to use a pulmonic valve because Bessler et al. and the state of the art fails to teach or suggest use of a pulmonic valve in the context of the combination recited in claim 18.**

In Appellant's Answer, Appellant argued that Bessler et al. does not teach or suggest a pulmonic heart valve in the context of the combination of claim 18.

The Examiner responded to Appellant's Arguments by stating, at pages 5-6 of the Examiner's answer, that,

"Applicant's arguments filed 9/24/04 have been fully considered but they are not persuasive with respect to claim 18. Applicant contends that the Bessler valve prosthesis cannot be substituted with a pulmonic valve. However, applicant's specification fails to provide any criticality as to what tissue is used for the claimed prosthesis, see for example page 6, lines 4, 5."

Appellant disagrees with the Examiner's Answer that (1) Appellant's arguments do not distinguish claim 18 over Bessler et al., and (2) criticality in the specification as to what tissue is used for the claimed prosthesis is required for patentability of claim 18.

**(i) Appellant's arguments distinguish between the structure of claim 18 and Bessler et al.**

The mere fact that Bessler teaches the use of certain types of heart valves does not result in the use of another type of heart valve being obvious. Significantly, the Final Office Action even admitted that Bessler et al. fails to disclose the use of a pulmonic animal heart valve, as recited in claim 18. Without the benefit of any prior art teaching or suggestion, a conclusion was made that it would have been obvious matter of design

choice to modify the type of valve used in Bessler et al. to a pulmonic valve. The Examiner's Answer now attempts to obscure further the deficiencies of Bessler et al. relative to the structural differences between the combination of claim 18 and Bessler et al. by mischaracterizing Appellant's arguments as being a type of argument requiring support by affidavit or declaration.

The statements made in support of the structural differences are not attorney arguments in the manner suggested in MPEP 716(c). In sharp contrast, the statements made in Appellant's Appeal Brief distinguish the structure recited in claim 18, which includes a pulmonic heart valve, from the teachings of Bessler et al. Appellant's Appeal Brief identified several differences between a pulmonic valve and the valves taught by Bessler et al., including that an aortic valve includes coronaries and generally has thicker leaflets than a pulmonic valve. The pulmonic valve corresponds to a heart valve that separates the right ventricle from the pulmonary artery in an animal. Accordingly, the arguments made in Appellant's appeal brief identify distinguishing structural differences between claim 18 and the teachings of Bessler et al. Moreover, the structural differences presented in Appellant's Appeal Brief and the absence of the prior art containing a teaching or motivation to employ a pulmonic heart valve, in the context of the claimed combination recited in claim 18, weighs on the side of non-obviousness and, therefore, should be considered as relevant.

The Examiner's answer further states that "Applicant's representative contends that the pulmonic valve has inherent structural features, but fails to point out where in the disclosure these distinguishing features are present." The term "inherent" by definition means, "existing in someone or something as a natural or inseparable quality

or right.” Webster’s New World Dictionary of the American Language, 1976. As mentioned above, a pulmonic heart valve is a particular anatomic structure and thus includes all structural and functional features existing in such structure. Because claim 18 recites that the heart valve prosthesis comprises a pulmonic valve, those skilled in the art understand, and are placed on notice of, which particular anatomical structure the claimed combination includes. Since for the reasons stated herein and in Appellant’s Appeal Brief, the Examiner has failed to present an adequate basis for obviousness based on prior art, the rejection of claim 18 should be reversed.

**(ii) Criticality in the specification is not a requirement for patentability.**

In response to Appellant’s contention that claim 18 is not obvious in view of the teachings of Bessler et al., the Examiner’s Answer also argues that Appellant’s specification fails to provide any criticality as to what tissue is used for the claimed prosthesis. The requirements for patentability are novelty, usefulness, and unobviousness as set forth in 35 U.S.C. Section 101, 102, and 103 *In re Ratti*, 123 U.S.P.Q. 349, 352 – 353 (CCPA 1959). Criticality is not required for patentability. The Examiner has failed to produce any rule, statute or other legal precedent that would require the specification to provide any criticality in the instant situation. In the absence of a statute, federal rule or legal precedent, the rejection of claim 18 should be reversed.

3. **Claim 54 is not obvious over Bessler et al.**

With respect to claim 54, the Examiner's Answer presents new arguments that "Claim 54 is obvious over Bessler et al. for the reasons mentioned above, because the body portion 102 clearly has a greater diameter than thee [sic] enclosure 103." However, the structure of Bessler et al. identified in the Examiner's Answer actually correspond to a catheter 102 and a pusher member 103 that is used to eject the valve 101. This is in sharp contrast to the structural and functional features of the combination recited in claim 54, wherein the cylindrical enclosure extends from the body portion and terminates in the open end and the body portion has a greater diameter than the cylindrical enclosure.

4. **Examiner's contention regarding Claim 17 states new grounds for rejection.**

With respect to claim 17, the Examiner's answer states, without the benefit of a reference or taking official notice, that it is well known in the art that cloth coverings provide smoother surfaces over stent structures, in addition to providing suturing ability and a surface for tissue in growth to occur. In addition to this position being a new unsupported ground for rejection, the Examiner's statement appears on its face to be factually inaccurate or ambiguous, as a cloth covering is generally not smoother than a stent structure. Other reasons that teach against the combination of Vesely et al. and Bessler et al. are set forth at pages 17-18 of Appellant's Answer.

5. **Claim 50 is not obvious over the combination of Bessler et al. and Toro et al.**

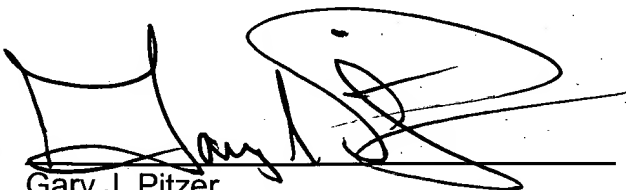
With respect to claim 50, the Examiner's answer contends that Appellant has argued individually against the combined Bessler et al. and Del Toro references.

Appellant's Appeal Brief does not argue against the references individually (see, e.g., page 20-22 of Appellant's Appeal Brief), as asserted in the Examiner's Answer. Instead, structural taught by the respective references are discussed in a manner to explain that there is not proper motivation to combine the teachings. For example, the Examiner's Answer contends that the Del Toro patent is utilized as a teaching to support incorporating a handle on the catheter system of Bessler et al. As stated in Appellant's Appeal Brief, since Del Toro does not teach a handle, but is instead discloses a manifold stabilizer (40) that is employed to space apart an outer shaft (32) from an inner shaft (36), there is no teaching, suggestion or motivation to incorporate a handle in the catheter system of Bessler et al., as suggested in the Examiner's Answer.

For the reasons stated above, the rejection of claims 2 through 19, 28, 50 and 53 through 57 should be reversed.

Please charge any deficiency or credit any overpayment in the fees for this Appeal Brief to Deposit Account No. 20-0090.

Respectfully submitted,

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